

## Food and Drug Administration, HHS

## § 803.3

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SOURCE: 60 FR 63597, Dec. 11, 1995, unless otherwise noted.

### Subpart A—General Provisions

#### § 803.1 Scope.

(a) This part establishes requirements for medical device reporting. Under this part, device user facilities, importers, and manufacturers, as defined in § 803.3, must report deaths and serious injuries to which a device has or may have caused or contributed, must establish and maintain adverse event files, and must submit to FDA specified followup and summary reports. Medical device distributors, as defined in § 803.3, are also required to maintain records of incidents (files). Furthermore, manufacturers and importers are also required to report certain device malfunctions. These reports will assist FDA in protecting the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.

(b) This part supplements and does not supersede other provisions of this subchapter, including the provisions of part 820 of this chapter.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[60 FR 63597, Dec. 11, 1995, as amended at 62 FR 13306, Mar. 20, 1997; 65 FR 4118, Jan. 26, 2000]

#### § 803.3 Definitions.

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) *Ambulatory surgical facility (ASF)* means a distinct entity that operates for the primary purpose of furnishing same day outpatient surgical services to patients. An ASF may be either an independent entity (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure or control of an entity). An ASF is subject to this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or regardless of whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the ASF must report that event regardless of the nature or location of the medical service provided by the ASF.

(c) *Become aware* means that an employee of the entity required to report has acquired information reasonably suggesting a reportable adverse event has occurred.

(1) Device user facilities are considered to have “become aware” when medical personnel, as defined in paragraph (s) of this section, who are employed by or otherwise formally affiliated with the facility, acquire such information about a reportable event.

(2) Manufacturers are considered to have become aware of an event when:

(i) Any employee becomes aware of a reportable event that is required to be reported within 30 days or that is required to be reported within 5 days under a written request from FDA under § 803.53(b); and

(ii) Any employee, who is a person with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or a person whose duties relate to the collection and reporting of adverse events, becomes aware that a reportable MDR event or events, from

any information, including any trend analysis, necessitate remedial action to prevent an unreasonable risk of substantial harm to the public health.

(3) Importers are considered to have become aware of an event when any employee becomes aware of a reportable event that is required to be reported by an importer within 30 days.

(d) *Caused or contributed* means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of:

- (1) Failure;
- (2) Malfunction;
- (3) Improper or inadequate design;
- (4) Manufacture;
- (5) Labeling; or
- (6) User error.

(e)(1) *Device family* means a group of one or more devices manufactured by or for the same manufacturer and having the same:

- (i) Basic design and performance characteristics related to device safety and effectiveness,
- (ii) Intended use and function, and
- (iii) Device classification and product code.

(2) Devices that differ only in minor ways not related to safety or effectiveness can be considered to be in the same device family. Factors such as brand name and common name of the device and whether the devices were introduced into commercial distribution under the same 510(k) or premarket approval application (PMA), may be considered in grouping products into device families.

(f) *Device user facility* means a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility as defined in paragraphs (b), (l), (t), (u), and (v), respectively, of this section, which is not a “physician’s office,” as defined in paragraph (x) of this section. School nurse offices and employee health units are not device user facilities.

(g) *Distributor* means, for the purposes of this part, any person (other than the manufacturer or importer) who furthers the marketing of a device from the original place of manufacture to

the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper or labeling of the device or device package. One who repackages or otherwise changes the container, wrapper, or labeling, is a manufacturer under paragraph (o) of this section.

(h) [Reserved]

(i) *Expected life* of a device (required on the manufacturer’s baseline report) means the time that a device is expected to remain functional after it is placed into use. Certain implanted devices have specified “end of life” (EOL) dates. Other devices are not labeled as to their respective EOL, but are expected to remain operational through maintenance, repair, upgrades, etc., for an estimated period of time.

(j) *FDA* means the Food and Drug Administration.

(k) *Five-day report* means a medical device report that must be submitted by a manufacturer to FDA pursuant to §803.53, on FDA Form 3500A or electronic equivalent as approved under §803.14, within 5 work days.

(l) *Hospital* means a distinct entity that operates for the primary purpose of providing diagnostic, therapeutic (medical, occupational, speech, physical, etc.), surgical and other patient services for specific and general medical conditions. Hospitals include general, chronic disease, rehabilitative, psychiatric, and other special-purpose facilities. A hospital may be either independent (e.g., not a part of a provider of services or any other facility) or may be operated by another medical entity (e.g., under the common ownership, licensure or control of another entity). A hospital is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the hospital must report that event regardless of the nature or location of the medical service provided by the hospital.

(m) *Importer* means, for the purposes of this part, any person who imports a device into the United States and who furthers the marketing of a device

from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. One who repackages or otherwise changes the container, wrapper, or labeling, is a manufacturer under paragraph (o) of this section.

(n) *Malfunction* means the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed, as defined in § 801.4 of this chapter.

(o) *Manufacturer* means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. The term includes any person who:

(1) Repackages or otherwise changes the container, wrapper or labeling of a device in furtherance of the distribution of the device from the original place of manufacture;

(2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications;

(3) Manufactures components or accessories which are devices that are ready to be used and are intended to be commercially distributed and intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient; or

(4) Is the U.S. agent of a foreign manufacturer.

(p) *Manufacturer or importer report number* means the number that uniquely identifies each individual adverse event report submitted by a manufacturer or importer. This number consists of three parts as follows:

(1) The FDA registration number for the manufacturing site of the reported device, or the registration number for the importer. (If the manufacturing site or the importer does not have a registration number, FDA will assign a temporary MDR reporting number

until the site is officially registered. The manufacturer or importer will be informed of the temporary number.);

(2) The four-digit calendar year in which the report is submitted; and

(3) The five-digit sequence number of the reports submitted during the year, starting with 00001. (For example, the complete number will appear 1234567-1995-00001.)

(q) *MDR* means medical device report.

(r) *MDR reportable event* (or *reportable event*) means:

(1) An event about which user facilities become aware of information that reasonably suggests that a device has or may have caused or contributed to a death or serious injury; or

(2) An event about which manufacturers or importers have received or become aware of information that reasonably suggests that one of their marketed devices:

(i) May have caused or contributed to a death or serious injury; or

(ii) Has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(s) *Medical personnel*, as used in this part, means an individual who:

(1) Is licensed, registered, or certified by a State, territory, or other governing body, to administer health care;

(2) Has received a diploma or a degree in a professional or scientific discipline;

(3) Is an employee responsible for receiving medical complaints or adverse event reports; or

(4) Is a supervisor of such persons.

(t)(1) *Nursing home* means an independent entity (i.e., not a part of a provider of services or any other facility) or one operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity) that operates for the primary purpose of providing:

(i) Skilled nursing care and related services for persons who require medical or nursing care;

(ii) Hospice care to the terminally ill; or

(iii) Services for the rehabilitation of the injured, disabled, or sick.

(2) A nursing home is subject to this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the nursing home must report that event regardless of the nature, or location of the medical service provided by the nursing home.

(u)(1) *Outpatient diagnostic facility* means a distinct entity that:

(i) Operates for the primary purpose of conducting medical diagnostic tests on patients;

(ii) Does not assume ongoing responsibility for patient care; and

(iii) Provides its services for use by other medical personnel. (Examples include diagnostic radiography, mammography, ultrasonography, electrocardiography, magnetic resonance imaging, computerized axial tomography and in-vitro testing).

(2) An outpatient diagnostic facility may be either independent (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An outpatient diagnostic facility is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient diagnostic facility must report that event regardless of the nature or location of the medical service provided by the outpatient diagnostic facility.

(v)(1) *Outpatient treatment facility* means a distinct entity that operates for the primary purpose of providing nonsurgical therapeutic (medical, occupational, or physical) care on an outpatient basis or home health care setting. Outpatient treatment facilities include ambulance providers, rescue services, and home health care groups. Examples of services provided by outpatient treatment facilities include: Cardiac defibrillation, chemotherapy, radiotherapy, pain control, dialysis, speech or physical therapy, and treatment for substance abuse.

(2) An outpatient treatment facility may be either independent (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An outpatient treatment facility is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient treatment facility must report that event regardless of the nature or location of the medical service provided by the outpatient treatment facility.

(w) *Patient of the facility* means any individual who is being diagnosed or treated and/or receiving medical care at or under the control or authority of the facility. For the purposes of this part, the definition encompasses employees of the facility or individuals affiliated with the facility, who in the course of their duties suffer a device-related death or serious injury that has or may have been caused or contributed to by a device used at the facility.

(x) *Physician's office* means a facility that operates as the office of a physician or other health care professional (e.g., dentist, chiropractor, optometrist, nurse practitioner, school nurse offices, school clinics, employee health clinics, or free-standing care units) for the primary purpose of examination, evaluation, and treatment or referral of patients. A physician's office may be independent, a group practice, or part of a Health Maintenance Organization.

(y) [Reserved]

(z) *Remedial action* means, for the purposes of this subpart, any action other than routine maintenance or servicing, of a device where such action is necessary to prevent recurrence of a reportable event.

(aa) [Reserved]

(bb)(1) *Serious injury* means an injury or illness that:

(i) Is life-threatening;

(ii) Results in permanent impairment of a body function or permanent damage to body structure; or

(iii) Necessitates medical or surgical intervention to preclude permanent

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impairment of a body function or permanent damage to a body structure.

(2) *Permanent* means, for purposes of this subpart, irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

(cc) *Shelf life*, as required on the manufacturer's baseline report, means the maximum time a device will remain functional from the date of manufacture until it is used in patient care. Some devices have an expiration date on their labeling indicating the maximum time they can be stored before losing their ability to perform their intended function.

(dd) [Reserved]

(ee)(1) *User facility report number* means the number that uniquely identifies each report submitted by a user facility to manufacturers and FDA. This number consists of three parts as follows:

(i) The user facility's 10-digit Health Care Financing Administration (HCFA) number (if the HCFA number has fewer than 10 digits, fill the remaining spaces with zeros);

(ii) The four-digit calendar year in which the report is submitted; and

(iii) The four-digit sequence number of the reports submitted for the year, starting with 0001. (For example, a complete number will appear as follows: 1234560000-1995-0001.)

(2) If a facility has more than one HCFA number, it must select one that will be used for all of its MDR reports. If a facility has no HCFA number, it should use all zeros in the appropriate space in its initial report (e.g., 0000000000-1995-0001) and FDA will assign a number for future use. The number assigned will be used in FDA's record of that report and in any correspondence with the user facility. All zeros should be used subsequent to the first report if the user does not receive FDA's assigned number before the next report is submitted. If a facility has multiple sites, the primary site can report centrally and use one reporting number for all sites if the primary site provides the name, address and HCFA number for each respective site.

(ff) *Work day* means Monday through Friday, excluding Federal holidays.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4118, Jan. 26, 2000; 66 FR 23156, May 8, 2001]

EFFECTIVE DATE NOTE: At 61 FR 38347, July 23, 1996, in §803.3, paragraph (n)(4) was stayed indefinitely.

### § 803.9 Public availability of reports.

(a) Any report, including any FDA record of a telephone report, submitted under this part is available for public disclosure in accordance with part 20 of this chapter.

(b) Before public disclosure of a report, FDA will delete from the report:

(1) Any information that constitutes trade secret or confidential commercial or financial information under §20.61 of this chapter;

(2) Any personal, medical, and similar information (including the serial number of implanted devices), which would constitute an invasion of personal privacy under §20.63 of this chapter. FDA will disclose to a patient who requests a report, all the information in the report concerning that patient, as provided in §20.61 of this chapter; and

(3) Any names and other identifying information of a third party voluntarily submitting an adverse event report.

(c) FDA may not disclose the identity of a device user facility which makes a report under this part except in connection with:

(1) An action brought to enforce section 301(q) of the act, including the failure or refusal to furnish material or information required by section 519 of the act;

(2) A communication to a manufacturer of a device which is the subject of a report required by a user facility under §803.30; or

(3) A disclosure to employees of the Department of Health and Human Services, to the Department of Justice, or to the duly authorized committees and subcommittees of the Congress.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4119, Jan. 26, 2000]